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EXAMINER	
BLAND, LAYLA D	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,562	RAUTONEN ET AL.	
	Examiner	Art Unit	
	Layla Bland	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-14,16-28 and 30-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-14,16-28 and 30-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a response to applicant's amendment filed October 3, 2007, wherein claims 2-4, 15, and 29 are cancelled, claims 1, 6-14, 16, 17, 19-28, 31-33 are amended, and new claim 34 is added. This application claims benefit to Finnish Patent Application No. FI 200321660, filed on September 17, 2003. Claims 1, 5-14, 16-28, and 30-34 are pending in this application and are examined on the merits herein.

In view of the cancellation of claims 2-4, 15 and 29, all rejections with respect to those claims in the previous office action are withdrawn.

Applicant's amendment submitted October 3, 2007, overcomes the objections to the drawings and the specification.

Applicant's amendment submitted October 3, 2007, overcomes the objections to claims 7, 17-25, and 31-33 for being in improper multiple dependent form.

Applicant's amendment submitted October 3, 2007, overcomes the rejection of claims 8-11 and 13 under 35 USC 112, second paragraph, as being indefinite.

The rejection of claims 1-6, 8, 12-16, 26-28 and 30 under 35 USC 102(a) and 102(e) as being anticipated by Rautonen et al. is withdrawn in view of applicant's submission of the priority document, Finnish Patent Application 20021660, filed September 17, 2002.

The rejection of claims 1-6, 8, 12-16, 26-28 and 30 under the judicially created doctrine of obviousness-type double patenting over claims 1-6, 8, 12-16, 26-28 and 30

of copending Application No. 10/341,748 is withdrawn in view of applicant's submission of a provisional terminal disclaimer.

The following are new or modified rejections not made of record in the previous office action:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing the pH throughout the colon and increasing the amount of butyrate in the colon, does not reasonably provide enablement for treating, managing, or preventing lactose intolerance, food allergy, inflammatory bowel disease, or celiac disease using polydextrose. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8

USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to the prevention of lactic acid accumulation using polydextrose. Thus, the claims taken together with the specification imply that polydextrose can be used to prevent and treat anything associated with lactic acid accumulation, including such embodiments as lactose intolerance and inflammatory bowel disease.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Polydextrose is known to have physiological effects similar to those of dietary fiber, including decrease in fecal pH and increased short-chain fatty acid production. Polydextrose is known to increase *Lactobacillus* and *Bifidobacterium* species in the colon, but Hove, et al. (Am J Clin Nutr 1994; 59: 74-9, of record) have shown that the

presence of lactic acid bacteria in the colon does not change the pattern of colonic fermentation or the degree of intestinal lactose malabsorption [abstract]. In light of the teachings of Hove, et al., ingestion of polydextrose cannot be expected to prevent lactose intolerance. Known treatments for food allergy and celiac disease are limited to simply avoiding the foods which cause the problem [Merck manuals online, of record].

The claims also encompass such embodiments as reducing the risk of inflammatory bowel disease. Inflammatory bowel disease has more than one cause (World J. Gastroenterol. 2006 Aug 14; 12(30): 4807-12, abstract) and thus the risk cannot be predictably reduced using a single type of agent.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided a working example for increasing the concentration of butyrate and decreasing the concentration of branched VFAs in healthy humans.

However, the specification does not provide guidance or working examples for the prevention of lactose intolerance, food allergies, inflammatory bowel disease, celiac disease or any other condition. No guidance is presented as which amount and frequency of dosage of polydextrose would be enough to prevent or affect a change in the above conditions.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the wide variety of conditions to be treated, the variation in causes of those conditions, and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5-14, 16-28, and 30-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (and all dependent claims) recites the limitation "a method for the therapeutic treatment or prophylactic treatment of a subject suffering from or subject to a risk of lactic acid accumulation..." The claim is drawn only to the treatment of a subject and does not specify which condition or disease is being treated. Thus is it impossible to determine the metes and bounds of the claim.

Claim 23 recites the limitation "sour food or feed product." It is unclear which foods or feeds are considered sour; thus, it is impossible to determine the metes and bounds of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-13, 19, 27, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Jie et al. (Am J Clin Nutr 2000, 72:1503-9, of record).

Jie et al. teach a study in which 4-12 grams of polydextrose per day were consumed by volunteers in order to study the physiologic effects. The polydextrose used was Litesse, provided by Danisco Cultor [page 1504, first paragraph], which is purified. Fecal pH decreased proportionally to polydextrose intake. Short-chain fatty acid production (butyrate) increased with polydextrose ingestion. *Bacteroides* (infection-causing bacteria) species decreased and *Lactobacillus* and *Bifidobacterium* (lactic acid bacteria) species increased. [page 1503, Results] Jie et al. also teach that polydextrose is partially fermented in the large intestine and fermentation of polydextrose leads to diminished putrefactive microflora and suppressed production of carcinogenic metabolites [page 1503, column 2, lines 13-19]. A high fecal output and low bowel pH can suppress the production of enteric toxins, which plays an important role in the prevention of diverticulosis and reduces the risk of bowel cancer [page 1506, column 2, lines 16-18].

Jie et al. are silent regarding the amount of lactic acid in the colon. However, the dosage taught by Jie et al. encompasses the daily dose of 10g per day exemplified in the instant specification.

The instant specification defines "imbalanced" fermentation as a situation wherein the energy available for bacteria in the colon is not distributed evenly along the colon, which leads to high amounts of lactic acid in the colon [page 9]. Thus, it is considered that any person who has eaten or who is likely to eat rapidly digestible foods (such as starch) is at risk of imbalanced colon fermentation and lactic acid accumulation.

Because Jie et al. teach the administration of the same compound, in the same dosage, to the same patient population, claims 1, 5-13, 19, 27, and 28 are anticipated by Jie et al.

Claims 1, 5-14, 16-19, 21, 22, 26-28, and 30-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Olinger et al. (WO 00/40101, published July 13, 2000, of record).

Olinger et al. teach a dietetic chocolate composition sweetened by a composition which includes 10-90% by weight of maltitol, 9-89% by weight of lactitol and 1-55% by weight of polydextrose [page 4, lines 9-20]. The composition exhibits a surprisingly high degree of sweetness relative to what would be expected from a simple mixture of the sweeteners [page 8, lines 28-31], which shows a synergistic relationship. A specific example [page 12, Table 1, Example 4] gives a composition comprising 12.50% lactitol

and 26.50% polydextrose. This is a ratio of roughly 1:2 polyol to polydextrose and therefore meets the limitations of claim 30. Olinger et al. also teach their composition can be made from purified polydextrose, unpurified polydextrose, hydrogenated polydextrose or a mixture thereof [claim 20]. The dietetic chocolate products were tasted (administered) [page 9, lines 11-19].

The instant specification defines "imbalanced" fermentation as a situation wherein the energy available for bacteria in the colon is not distributed evenly along the colon, which leads to high amounts of lactic acid in the colon [page 9]. Thus, it is considered that any person who has eaten or who is likely to eat rapidly digestible foods (such as starch) is at risk of imbalanced colon fermentation and lactic acid accumulation.

Olinger et al. are silent on the accumulation of lactic acid in the colon. However, It is well known that polydextrose has physiologic effects similar to those of dietary fiber (see Jie, et al. as above) and is fermented in the colon; this is an inherent property. Thus, the claims are anticipated by Olinger et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jie et al. (Am J Clin Nutr 2000, 72:1503-9, of record).

Jie et al. teach as set forth above.

Jie et al. do not teach the administration of polydextrose in a food product.

It would have been obvious to one of ordinary skill in the art to administer polydextrose in a food product and to administer polydextrose to subjects having conditions associated with digestive and bowel health. Jie et al. teach that consumption of polydextrose improved bowel function, softened the feces, improved the ease of defecation, promoted the proliferation of favorable intestinal microflora and decrased the pH of the bowel [page 1508, last paragraph]. The skilled artisan could easily conceive of administering a compound that is useful for digestive and bowel health into a food composition. Furthermore, it is obvious to administer a composition that is useful for digestive and bowel health to subjects having conditions associated with digestive and bowel health, such as celiac disease and food allergy, or other conditions which affect digestive and bowel health.

Response to Arguments

Applicant's arguments filed October 3, 2007 have been fully considered but they are not persuasive.

Applicant argues that that utilization of polydextrose in the claimed method of treating a subject is supported by the specification and thus the claims are enabled.

The specification does not provide sufficient guidance for the treatment and prevention of lactose intolerance, food allergy, inflammatory bowel disase or celiac disease using polydextrose, as set forth above.

Applicant argues that the claims are drawn to administering a food or feed product containing polydextrose to a subject suffering lactic acid accumulation, and thus the claims are not anticipated by Jie et al. or Olinger et al.

This is not an accurate description of the claimed subject matter. The claims are drawn to the treatment of a subject suffering from or subject to a risk of lactic acid accumulation, and not all of the claims require a food product.

Applicant argues that Jie et al. does not suggest or describe the use of polydextrose to subjects suffering from lactic acid accumulation and does not disclose that polydextrose prevents accumulation of lactic acid.

As set forth above, the claims are drawn to the treatment of a subject suffering from or subject to a risk of lactic acid accumulation, which encompasses the population treated by Jie et al. Furthermore, the method of Jie et al. inherently prevents lactic acid accumulation since the method steps are the same as the instant method steps. Note that even the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it related to the claimed invention herein. Further, note that " by preventing accumulation of lactic acid" is considered to mechanism of action of a

treatment. Applicant's recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps. Note that a mechanism of action of a treatment would not by itself carry patentable weight if the prior art teaches the same or nearly the same method steps.

The above response is also applicable to applicant's arguments with respect to Olinger et al.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Bland whose telephone number is (571) 272-9572. The examiner can normally be reached on M-R 8:00AM-5:00PM UST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Layla Bland
Patent Examiner
Art Unit 1623
November 8, 2007

Shaojia Anna Jiang

11/15/07

Supervisory Patent Examiner
Art Unit 1623
November 8, 2007